APR 2 8 2014

510(K) SUMMARY

510(K) Number K132042

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Date Prepared: 05 November 2013

Trade Name: Amblyz™

Classification:
Classification Name: Shield, eye, ophthalmic
Medical Specialty: Ophthalmic
Product Code: HOY
Device Class: I
Regulation Number: 886.4750
Panel: Ophthalmic

Predicate Devices:

- LCG (Liquid Crystal Glasses) System; cleared under K050856; Product Code HOY; Regulation Number 886.4750

Intended Use / Indication for Use:

The Amblyz™ System is an electronic shutter module intended to provide occlusions of the eye in an intermittent fashion.

Technological Characteristics:

The Amblyz™ system uses operation principles equivalent to those of the legally marketed LCG System. The device utilizes a Liquid Crystal and electronics technology to create an electronic shutter module that enables the exercise of the amblyopic eye combining with rest periods of the sound eye. There is no control mechanism change

and no change in energy type. All changes that do exist are presented in the comparison table presented below under 'substantial equivalence'.

Device Description:

The Amblyz™ device is an optical eyewear using a Liquid Crystal lens and electronics technology that acts as an intermittent shutter. The shutter incorporated in the optical lens performs an occlusion of the sound eye in an intermittent mode by changing the lens from a clear to an opaque state via electronic control. The system incorporates the following components (as detailed in chapter 12 of this submission):

1. ***Spectacle Frame***
   The Spectacle frame designed to hold both the liquid crystal lens and the refractive lens. The frame is made of biocompatible durable plastics.
2. ***Liquid Crystal Shutter (LCS)***
   The LCS lens, which functions as an electronic shutter is bundled in the glasses frame. Controlled by the microcontroller on the PCB, the designated LCS performs repetitive occlusion and transparent sessions during which the lens is fully transparent ("OFF" state) when no voltage is applied and turns opaque ("ON" state) when voltage is applied.
3. ***Earpieces***
   The ear pieces are the part of the spectacle frame that extends from the hinges and to the back end of the device
4. ***Nose Piece***
   Nosepiece increases the distance between the nose and the spectacle frame, The nosepiece is detachable from the spectacle frame and the user can choose if to use it or not.
5. ***Clip to Hold Refractive Lens***
   A plastic clip that holds the optic lenses (if needed).
6. ***Micro-USB Connector***
   During normal operation the connector is used only to charge the glasses. X6D technicians also use this connector to upload firmware to the electronic control - for tests and/or updates.
7. ***LED Indicator***
   The Amblyz™ is equipped with an orange LED. The LED should be OFF when in normal operation and ON when properly connected to the USB charger and charging. Once the battery is fully charged, the LED indicator will turn OFF, even if Amblyz™ glasses are still connected to the USB charger. A flashing LED light indicates that the battery is low and charging is needed.
8. ***ON/OFF Switch***
   A mechanical rotary switch used only to power ON the glasses, an action that is performed only once, by the optician who initially sets up the glasses.
9. ***Programming Button***
   The programming button is a simple push button, located next to the ON switch. Push button is used for setting the eye to be occluded. This operation is performed only once, by the optician who initially sets up the glasses.
10. ***Amblyz™ onboard Software***

An onboard software (referred to as "firmware") controls the Amblyz™ glasses and their function. The purpose of the software onboard the Amblyz™ glasses unit, is to allow the initial setting, and then after continuously deliver the therapy sequence without any option for user tampering. Other "house holding" functions of the software are to alert on low battery state, support the "watch-dog" component that resets the glasses in case of error.

11. ***Amblyz™ Technician Software***
Amblyz™ PC Maintenance (Technician) Software is intended to be used only by qualified X6D personnel for the purpose of reprogramming / upgrading the onboard Amblyz™ software.

Substantial Equivalence:

The table below presents the comparison between the Amblyz™ System and the legally marketed device - the LCG System.

	Amblyz™ System	**LCG System (Predicate)**
Indications	The Amblyz™ System is an electronic shutter module intended to provide occlusions of the eye in an intermittent fashion. (As the LCG)	The LCG (Liquid Crystal Glasses) System is an electronic shutter module intended to provide occlusions of the eye in an intermittent fashion.
Technological Characteristics	Computer derived, electrical and Liquid Crystal technology. A Liquid Crystal Module (LCM) lens covers a spectacle unit lens, which is intermittently occluded when voltage is applied. (As the LCG)	Computer derived, electrical and Liquid Crystal technology. A Liquid Crystal Module (LCM) lens covers a spectacle unit lens, which is intermittently occluded when voltage is applied. .
Materials	The Amblyz™ System's components that come with direct contact with the patient for a continuous duration of use are the Spectacle Frame (comprised of front frame, nose piece, ear handles and clip). ▪ The front frame is made of durable and biocompatible plastic PC Makrolon 2458. ▪ The nose piece is made of Texin RXT50D ▪ The Amblyz™ System's handle comprises Elastosil Colour Paste Pt Yellow Ral 1021 and Elastosil R 401/70 All the above materials conform to	The LCG System's parts that come in direct contact with the patient and intended for a continuous duration of use are the Spectacle Frame and its Strap. ▪ The Spectacle Frame is made of a durable and biocompatible plastic Grilamid TR 90. ▪ The Strap is made of biocompatible Thermoplastic polyurethanes (TPU) Carbothane®.

	Amblyz™ System	LCG System (Predicate)
	applicable biocompatibility and flammability requirements.	
Mode of Action	▪ The patient is wearing the AMBLYZ™ (spectacle) Unit. ▪ Intermittent occlusions are performed. ▪ ON/OFF switch is used by technician only – in course of user operation the glasses are always ON	▪ The patient is wearing the LCG (spectacle) Unit. ▪ Intermittent occlusions are performed. ▪ ON/OFF switch is activated by a touch sensor on the glasses that is activated upon wearing the glasses
Set-Up	One time only "press button" set-up - done by healthcare professional	Set-up via dedicated PC software.
Charging	Mini-USB connection to computer or any other USB port or wall charger (not included in system)	Mini-USB connection to dedicated charging box
Compliance monitoring	None	Glasses mounted sensor monitors wear time
Occlusion Pattern	1) Occlusion is performed in an intermittent fashion, enabling rest periods 2) Total occlusion time is approximately 50% of the time 3) Occlusion pattern is fixed: 30 seconds and rest period is 30 seconds.	1) Occlusion is performed in an intermittent fashion, enabling rest period 2) Total occlusion time is approximately 50% of the time: 3) Occlusion pattern is quasi-random, with occlusion periods varying between 12 up to 35 seconds.
Indicators	(On glasses only) A flashing LED light indicates when battery is low. Constant LED light indicates charging. Shutter Lenses rapid flashing indicate correct connection to charger.	1. None on glasses 2. The reporting box indicates actual and prescribed wear time and present smiley/sadly icons that indicate compliance.
Design	1. Frame dimensions: L129 x W129 x H40 mm 2. Weight: 36,4 g 3. The electronics and battery are housed within the frame 4. Optic lenses on clip, can be detached for cleaning and/or replacement 5. Viewing angle (pantoscopic angle) provides a 6 degrees	1. Frame dimensions: L120xW120xH34mm 2. Weight: ~35gr 3. The electronics and battery are housed in the spectacles strap. 4. Optic lenses are coupled (glued) to device. 5. Viewing angel zero (pantoscopic angel not

	Amblyz™ System	LCG System (Predicate)
	pantoscopic angle	applied)
Performance	1. Operation time without charge: over 48 hours 2. Charging time: less than 2 hours 3. Lens transparency: 40% 4. Contrast ratio: Over 400	1. Operation time without charge: 20 hours 2. Charging time: 8 hours 3. Lens transparency: 40% 4. Contrast ratio: 1:300

Safety and Performance Testing

A series of safety and performance testing were performed:

- Electrical safety and electromagnetic compatibility testing according to IEC 60601-1 (and amendments), and IEC 60601-1-2 standards. The Amblyz™ has found to comply with the requirements of these standards. Certificate of Compliance to these standards is attached to this submission.
- Software verification and validation testing
- A set of in vitro (bench) performance testing:

Test Description	Results
Lens Impact Resistance/Drop Ball Test	The lenses cracked but did not shatter into pieces and therefore comply with standard requirements
Destructive Test	The LC lens glass was cracked and the liquid crystal was spread across the glass. Nevertheless, the laminated films completely held the LCM glass pieces. No change in the overall package and no glass residues were found. Test was performed on four lenses, all resulting in same findings
Charge/Discharge Test	Tests show, that glasses have more than enough operating time with the used battery.
Charging Time Test	All ten (10) test cases comply with the acceptance criteria
Climatic Testing	The samples sustained the specified environmental testing, no damage was noted.
Unpacked Drop Test	All samples have passed all visual and operating/performance checks after the drop
Cosmetic Resistance	No visual change on tested samples after the test was completed.
Sweat Resistance	No visual change observed on tested surfaces in all tested samples

Test Description	Results
Cleaning Resistance	No visual change observed on tested surfaces in all tested samples
Thermal Shock	All samples have passed all visual and operating/performance checks after the test
Electrical Characteristics Test	All tests passed successfully and meet acceptance criteria.

- Packaging Validation including the following tests:

Test Description	Results
Fall Test - Master Packaging	Functional and cosmetic inspections have passed successfully.
Fall Test - Retail Packaging	All samples passed and meet acceptance criteria
Transportation Vibration Test	After the completion of Transportation Vibration Test, units inside the carton box were subjected to functionality check. All test units passed the functionality check with no functionality and cosmetic problem.
Bump Test	After the completion of Bump Test, units inside the carton box were subjected to functionality check. All test units passed the functionality check with no functionality and cosmetic problem.

Biocompatibility Testing

According to the Blue Book Memo, G95-1, Use of International Standard ISO-10993, and ISO 10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, the components of the Amblyz™ glasses are categorized as surface device with Intact skin permanent (>30days) contact. The parts that come in direct contact with the patient and intended for a continuous duration of use are the Spectacle Nosepiece, Front frame (Case left & right) prescription frame, and the Amblyz™ Insert left & right part of the handle. Cytotoxicity testing was conducted on all the above, based on the requirements of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

Also, hazard analysis including risk level and solutions performed in compliance with ISO 14971:2012 for the entire system and for the software.

In conclusion, a series of in vitro, software, electrical safety, and biocompatibility test results demonstrate that the product has acceptable safety and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 28, 2014

X6D Ltd.
% Ms. Neta Landman
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P.O. Box 536

Re: K132042
Trade/Device Name: Amblyz™
Regulation Number: 21 CFR 886.4750
Regulation Name: Ophthalmic Eye Shield
Regulatory Class: Class I
Product Code: HOY
Dated: March 21, 2014
Received: March 31, 2014

Dear Ms. Landman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132042

Device Name
Amblyz

Indications for Use *(Describe)*
The AmblyzTM System is an electronic shutter module intended to provide occlusions of the eye in an intermittent fashion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Andrew Yang -S
2014.04.25
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K132042

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